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DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/291,227	04/13/99	HAYEK M	IAM467PA

HM22/1203
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EXAMINER	
FAULKNER, D	
ART UNIT	**PAPER NUMBER**
1617	6

DATE MAILED: 12/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant
09/291,227	Hayek
Examiner	**Group Art Unit**
Faulkner, D.	1617

☒ Responsive to communication(s) filed on *Sep 13, 1999* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12 and 14~~16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12 and 14~~16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

D Faulkner

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Declaration

1. The examiner acknowledges receipt of the declaration received on 9/13/99. The declaration has been considered, it has been persuasive to **remove Cerveny et al and Kim et al** abstracts, however it is not persuasive to remove all rejections of record.

2. The applicants (statements) concerning the 112 rejection have been considered but have not overcome the rejections (below) of record.

3. Claims 1-3 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cats and dogs, does not reasonably provide enablement for all companion animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The applicant has not described the term companion animals in a way that depicts the breadth of the claims. Subsequently, one of ordinary skill in the art would not be apprised of the nature of the invention, nor of the state of the prior art. The specification has not provided any direction as to how to calculate a crude protein. Therefore it would require undue experimentation to make the invention based on the content of the disclosure.

The applicant can overcome this rejection by limiting the language to the terms that applicant is enabled for. Applicant is enabled for those species particularly disclosed in the specification. See ex. P. 1 lines 7-10 therein. The determination of additional species for which

the claimed processes and compositions would be useful would require undue experimentation by one of ordinary skill in the art.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-8, 12, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicants refers to a method of enhancing immune response and improving overall health. The claims are indefinite as to conditions present in a host which are determinative of "overall health".

The expression overall health is indefinite as to what symptoms, conditions, or benefits are encompassed thereby. The applicant has not described term "overall health" in such a way as to show the breadth of the claims. Subsequently, one of ordinary skill in the art would not be apprised of the nature of the invention, nor of the state of the prior art. The specification has not provided any direction as to how to measure whether "overall health" has been obtained. Therefore it would require undue experimentation to use the invention based on the content of the disclosure.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al., Immunomodulating actions of carotenoid: AN 1994:321921 further in view of Anon, Ailment Specific dietary supplements, AN 97:19144 (both of record).

Jyonouchi et al., describes Immunodulating actions of carotenoid including lutein for humoral immune responses in animals. Humoral immune response include cell mediated immune responses. (See abstract) The claims differ in that Jyonouchi fails to describe the specific dietary supplements. Anon et al., describes the ailment specific dietary supplements with lutein in food products used for building stress immunity. (See title and abstract).

One of ordinary skill in the art would have found it obvious to modify the primary reference to include the supplement forms of Anon in the administration of lutein for animals as an immunodulatory activator, as demonstrated by Jyonouchi et al.

The motivation for combining the references is that they are equivalent compounds which are being administered for the same reason, building immunity.

7. It is appreciated that all of the upper amounts of administration for lutein are not explicitly disclosed by the references. However it would have been obvious to the artisan to optimize amounts in order to achieve effective results. Furthermore, while certain companion animals are Jyonouchi and Anon, i.e., mice and humans, the fact that each reference discloses

that the same characteristics of lutein functioning in immune system enhancement demonstrates that the average artisan would expect lutein to have the same effect in any warm blooded animal.

8. Claims 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biobusiness abstract 97:19144, Anon.

The abstract teaches that compositions comprising lutein are known in the art. The optimization of amounts of agents to be employed is considered within the skill of the artisan. Further, "intended use" of a composition e.g., to improve immune response in specified animals, is not considered to further limit claims drawn to compositions. See e.g., In re Hack 114, USPQ 161. It would have been obvious to one of ordinary skill in the art to utilize the lutein supplements of Anon in order to meet the composition as claimed by applicant. The motivation for using the supplement form is that such compositions are demonstrated in the prior art.

RESPONSE TO ARGUMENTS

9. Applicant's arguments filed 9/13/99 have been fully considered but they are not persuasive. Applicant states that neither references teach the administration of lutein supplement to companion animals such as dogs or cats. However mammalian species are represented by Jyonuchi and are not patentably distinct from the companion animals claimed by applicant. Since lutein is effective for mammalian species as demonstrated by Jyonuchi and anon it would be presumed to be effective for all species including companion animals such as dogs and cats.

10. Applicants data has been considered, however it does not clearly demonstrate an unexpected effect for the claimed invention.

The data that applicant has presented in the specification demonstrates that immune response is greater for animals administered lutein for a period of greater than 8 weeks. The prior art teaches benefits in immune response and in several characteristics which improve the health in mammals that are fed lutein. Since the results that applicant is claiming are expected and demonstrated in the prior art, applicants data has not overcome the rejection.

11. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth I n 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Faulkner whose telephone number is (703) 305-4043. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Don Adams, can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D.Faulkner:BL

11/26/99

MINNA MOEZIE
PRIMARY EXAMINER